

**A PROSPECTIVE CROSS- SECTIONAL STUDY OF
MEDICATIONS PRESCRIBED FOR THE TREATMEN OF
PATIENTS WITH TYPE-2 DIABETES MELLITUS IN
TIRUPUR DISTRICT**

Dissertation submitted to

THE TAMILNADU Dr. M.G.R.MEDICAL UNIVERSITY

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In partial fulfillment of the requirement for the award of the degree of

MASTER OF PHARMACY

In

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Submitted by

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THE ERODE COLLEGE OF PHARMACY & RESEARCH INSTITUTE

ERODE

APRIL - 2018



**Dedicated to the
Almighty
My Loving Family
And Friends**

EVALUATION CERTIFICATE

This is to certify that dissertation work entitled “**A PROSPECTIVE CROSS SECTIONAL STUDY OF MEDICATIONS PRESCRIBED FOR THE TREATMENT OF PATIENTS WITH TYPE-2 DIABETES MELLITUS IN TIRUPUR DISTRICT**” Submitted by **REG NO: 261640404** to THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY, CHENNAI, in partial fulfillment for the degree of **MASTER OF PHARMACY** is a bonafide thesis work carried out by the candidate at the department of pharmacy practice, The Erode college of pharmacy and Research institute, erode, was evaluated by us during the academic year **2017-2018**.

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The research work embodied in this dissertation work entitled “ **A PROSPECTIVE CROSS SECTIONAL STUDY OF MEDICATIONS PRESCRIBED FOR THE TREATMENT OF PATIENTS WITH TYPE-2 DIABETES MELLITUS IN TIRUPUR DISTRICT**” was carried out by me in the department of pharmacy practice, the erode college of pharmacy, erode, under the direct supervision of **Dr.R.SenthilSelvi., M.Pharm., Ph.D.,** the erode college of pharmacy, erode. Thos dissertation submitted to **THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY, CHENNAI,** as a partial fulfillment for the award of **degree in Master of Pharmacy** in pharmacy practice during the academic year 2017-2018. The work is original and has not been submitted in part or full for the award of any degree or diploma of this or any other university.

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ABBREVIATIONS

LIST OF ABEREVIATION

ACEI	Angiotensin Converting Enzyme Inhibitor
ADRS	Adverse Drug Reactions
AMPK	Adenosine Monophosphate Activated Protein Kinase
ATP	Adenosine Triphosphate
ARB	Angiotensin Receptor Blocker
AGI	Alpha Glucosidase Inhibitor
BG	Biguanide
BMI	Body Mass Index
CDC	Center for Disease Control
CHD	Cardiac Heart Disease
CES	Cholesterol Ester Synthetase
CNS	Central Nervous System
CVD	Cardio Vascular Disease
DBP	Diastolic Blood Pressure
DDIs	Drug Drug Interactions
DBP	Diastolic Blood Pressure
DDD	Defined Daily Dose
DM	Diabetes Mellitus
DPP4	DipepidylPeptidase Four Inhibitor
DKA	Diabetic ketoacidosis
EPI	Epidemiological Information Package
PG	Fasting Plasma Glucose

EFA	Free Fatty Acid
GDM	Gestational Diabetes Mellitus
GIP	Glucose Dependent Insulinotropic Peptide
GLP	Glucagon-Like Peptide
HDL	High Densitylipoprotein
HbA1C	Glycosylated Haemoglobin
ICMR	Indian Council of Medical Science
IDDM	Insulin Dependent Diabetes Mellitus
IFG	Impaired Fasting Glucose
LDL	Low Density Lipoprotein
LP(a)	Lipoprotein (a)
LPL	Lipoprotein Lipase
MF	Metformin
NIDDM	Non-Insulin Dependent Diabetes Mellitus
OADs	Oral Antidiabetic Drug
OGTT	Oral Glucose Tolerance Test
PAI-1	Plasminnogen Activator Inhibitor 1
PPG	Post Prandial Glucose
PPI	Post Prandial Insulin
SBP	Systolic Blood Pressure
SD	Standard Deviation
SU	Sulfonylurea
TC	Total Cholesterol

T1DM	Type 1 Diabetes Mellitus
WHO	World Health organization

ABSTRACT

BACKGROUND

Diabetes mellitus (DM) is an important public health problem in developing countries. Drug utilization study of anti-diabetic agents is of paramount importance to promote rational drug use in diabetics and make available valuable information for the healthcare team. The aim of study was to investigate the drug utilization pattern in type-2 diabetic patients.

PATIENT AND METHODS

A prospective, cross-sectional study was carried out in medicine outpatient at government hospital, tirupur for a period of six weeks. Patients who fulfilled inclusion criteria and had type-2 diabetes mellitus were included in the study. Data was analysed using Excel 2007

RESULT

A total 110 patients were enrolled in the study. In this study, type-2 diabetes was more prevalent in elder patient of age group 61-70 years[41(37.275%)]. Male patients were [52(47.24%)] while female patient were [58(52.73%)]. Most of the common utilized class of drugs was Biguanides 70% followed by Sulphonylureas 58.18%.

CONCLUSION

Metformin was the most utilized (70%) anti-diabetic agent for type-2 diabetes. The principal aim of this study is to facilitate the rational use of drugs in population.

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INTRODUCTION

INTRODUCTION

Diabetes mellitus is a national as well as global epidemic disease in terms of incidence, healthcare costs and overall complications as reported by the center for disease control (CDC)¹. Diabetes affects some 300 million people world-wide, and is on the increase. Chronic exposure to high blood glucose is a leading cause of renal failure, visual loss and a range of other types of tissue damage. Diabetes also predisposes to arterial disease, not least because it is often accompanied by hypertension, lipid disorders and obesity². Nearly 18.2 million Americans have Diabetes, yet only about two thirds of them have been diagnosed. The economic burden of DM approximated 132 million dollars in 2002, including direct medical and treatment costs as well as indirect costs attributed to disability and mortality³. It has estimated that the total number of people with diabetes in 2010 to around 50.8 million in India, rising to 87 million by 2030³.

DEFINITION

Diabetes mellitus is a heterogeneous group of diseases characterized by chronic elevation of glucose in the blood. It arises because the body is unable to produce enough insulin for its own needs, either because of impaired insulin secretion, impaired insulin action, or both⁴.

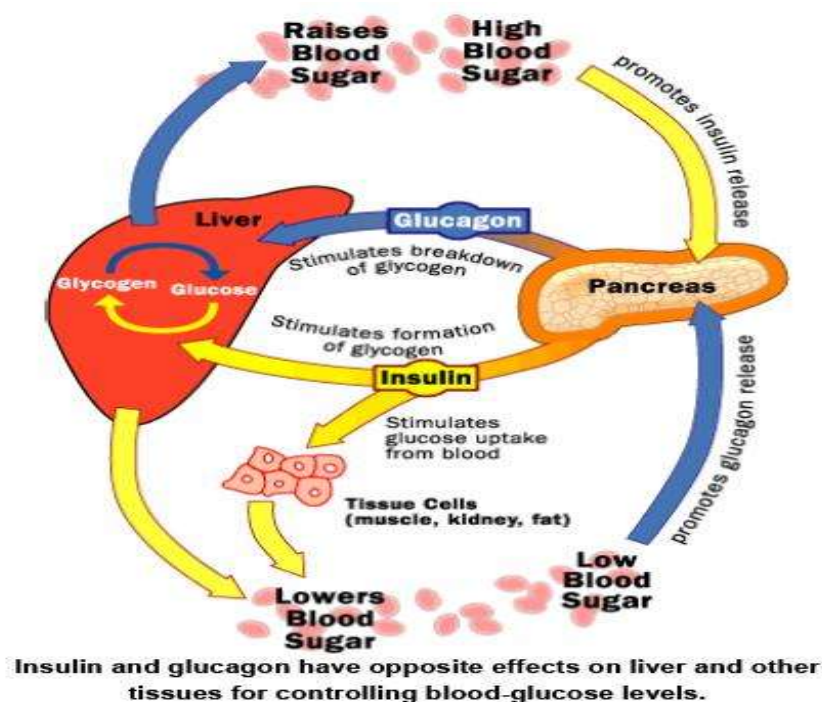
ROLE OF INSULIN AND GLUCAGON

Two hormones which responsible for the maintaining the balance of blood glucose is insulin and glucagon, which produced in the islets of pancreas⁵. Insulin is a hormone that is secreted by beta cells in the pancreas and facilitates storage of glucose as glycogen free fatty acid as triglycerides, amino acid as protein. It also inhibits the breakdown, of fat and protein and production of glucose and ketone by the liver. Glucagon on the other hand is secreted by alpha cells of pancreas islets and stimulate mobilization of glucose, free fatty acids as glycerol as well as stimulating hepatic uptake of amino acid and the conversion of their carbon skeletons to glucose.

This hormone also stimulates the production of ketone from free fatty acid. Glucose is the key regulator of insulin secretion although amino acids, ketones, certain nutrients, gastro intestinal peptidase and neurotransmitters also influence insulin secretion. Meals or other major stimuli induce bursts insulin secretion that may last for 3-4 hours before returning to baseline. After meal plasma insulin rises sharply and glucagon level declines there for the ratio of insulin to glucagon rises, as a result

- Dietary carbohydrate is stored in muscle and liver as glycogen.
- Free fatty acids stored as triglycerides in fat tissue.
- Protein metabolism shifts in the direction of protein synthesis

When all the nutrients have been assimilated and plasma glucose returns to its basal premeal level, plasma insulin level declines, glucagon level rises, and the insulin/glucagon ratio returns to pre meal level. These prevent excessive insulin action that might lower the blood glucose enough to cause hypoglycemia. Thus, an immediate rise, an early peak, and prompt fall in insulin secretion are characteristic of normal metabolism around the time of meal. Abnormalities in these patterns of insulin and glucagon secretions are early signs of islet dysfunction in diabetes mellitus⁶.



There are four cell types with the islets of Langerhans.

1. Insulin secreting beta cells, which are a key component of islets of Langerhans, are located in the center portion of the islets and are the predominant type (80% of the cells).
2. Glucagon secreting alpha cells (about 20% of the islet cells) are located mainly in the periphery.
3. The beta cells, which secrete somatostatins are located between these two cell types and are few in number.
4. Pancreatic polypeptide-secreting pp cells (also called F cells) are located mainly in the islets in the posterior lobe of pancreas.

Pancreatic islet function is abnormal in type 2 diabetes mellitus, the response to glucose by insulin and glucagon is inappropriate. The defect is evident early in the

development of the disease and can be observed in persons with pre diabetics. This believed to be due to abnormal islet function involving both alpha cells and beta cells⁷.

DIABETES AND ISLETS DYSFUNCTION

Type 2 diabetes characterized mainly by three pathophysiologic abnormalities.

- Peripheral insulin resistance
- Impaired insulin secretion
- Excessive hepatic glucose production⁸

As the disease progress, high levels of glucagon coupled with low levels of insulin drive excessive hepatic glucose production and the emergence of hyperglycemia. Pancreatic islets function is abnormal in type 2 diabetes⁹. It's found that United Kingdom prospective diabetes (UKPD) study indicated that by the time type 2 diabetes diagnosed, individual have already lost up to 50% of their beta cell function. Decline proceeds rate 6% per year⁹.

TYPES OF DIABETES MELLITUS

Out of many types of diabetes, the most common once are

I. Type 1 diabetes mellitus

- Immune mediated
- Idiopathic

II. TYPE 2 diabetes mellitus

III. Other specific type of diabetes

- Genetic defect of islet beta cell function
- Genetic defect of insulin action
- Disease of the exocrine pancreas
- Endocrinopathies

- Drug or chemical induced diabetes
- Infections
- Other genetic symptoms¹⁰

IV. Diabetes during pregnancy

TYPE 1 DM (IDDM)

Which occur due to either autoimmune T cell mediated B cell destruction or idiopathic reason, which leads to absolute deficiency of insulin. This is account for 10% of all diabetes cases and usually occurs in young age (below 30 years). Type 1 DM is characterized be faster onset of symptoms¹¹

TYPE 2 DM (NIDDM)

About 90% of total diabetes cases are type 2 DM and which more common above the age of 40. It is caused by deficient action of insulin due to decreased production, decreased insulin sensitivity to cells or both. The symptoms of type 2 DM are occur slowly in onset¹².

DIABETES DURING PREGNANCY

It is a form of glucose intolerance occurs during pregnancy. It is detected at 24 to 28 weeks of gestation and requires insulin injections.

The patients who are at increased risk of GDM belong to the following categories

- >25 years of age
- Over Weight
- First degree family history of diabetes
- Previous history of abnormal glucose metabolism
- Glycosuria
- Previous poor obstetric history
- Ethnicity associated with high prevalence of diabetes mellitus
- A previous large baby weighing more than 4 kg (91 bs)

Both the woman and the child pose a high risk due to gestational diabetes¹³.

OTHER SPECIFIC TYPES

Genetic defects of b-cell function, Genetic defects in insulin action, Diseases of the pancreas, Endocrinopathies, Drug- or chemical-induced, Infections¹⁴.

EPIDEMIOLOGY

TYPE 1 DM (IDDM)

Type 1 diabetes is caused by an absolute deficiency of insulin. This is account for 10% of all diabetes cases and usually occurs in young age (below 30 years). Type 1 DM is characterized by faster onset of symptoms. Affecting approximately 20 million people worldwide (American Diabetes Associated, 2001). Although type 1

Diabetes affects all age groups, the majority of individuals are diagnosed either at around the age of 4-5 years.

TYPE 2 DM (NIDDM)

About 90% of total diabetes cases are type 2 DM and which more common above the age of 40. It is caused by deficient action of insulin due to decreased production, decreased insulin sensitivity to cells or both.

The symptoms of type 2 DM are occur slowly in onset. There are approximately 1.4 million people with diagnosed type 2 diabetes in the UK, with a further 1 million having undiagnosed type 2 diabetes¹⁵.

ETIOLOGY

TYPE ONE DIABETES (10-15%)

Type 1 diabetes mellitus comprises several diseases of the pancreatic beta cells which leads to an absolute insulin deficiency¹⁶.

TYPE TWO DIABETES (85-90%)

Insulin resistance (overweight people), Inadequate insulin production (lean people), or combination of both¹⁷.

DIABETES DURING PREGNANCY

Diabetes diagnosed during pregnancy, increased health risk to mother and baby, may require insulin injection, goes away after birth but increased risk of developing type 2DM for mother and child¹⁸.

CLINICAL MANIFESTATIONS

Signs and symptoms

Diabetes symptoms vary depending on how much your blood sugar is elevated. Some people, especially those with prediabetes or type 2 diabetes, may experience symptoms initially. In type 1 diabetes, symptoms tend to come on quickly and be more severe. Some of the signs and symptoms of type 1 and type 2 diabetes include

Weakness

Increased thirst

Frequent urination

Extreme hunger

Unexplained weight loss

Presence of ketones in the urine (ketones are a byproduct of the breakdown of muscle and fat that happens when there's not enough insulin)

Fatigue

Blurred vision

Slow-healing sores

High blood pressure

Frequent infections, Such as gums or skin infections and vaginal or bladder Infections¹⁹

PATHOPHYSIOLOGY

Insulin is produced in the pancreatic B cells, initially as a polypeptide precursor (preproinsulin), then it converts to proinsulin and it converts to insulin by removal of 4 amino acids. Insulin secretion is stimulated by the glucose in the body, the response is started by the intake of nutrients and the release of gastrointestinal peptide hormones.

After released from pancreas insulin is entered in to portal circulation, insulin is metabolized by liver and kidney.

In type I diabetes mellitus is an deficiency if insulin that leads to hepatic glucose output by uncontrolled hepatic glucogenolysis and gluconeogenesis, and glucose uptake is decreased in tissues which lead to hyperglycemia.

In type 2 diabetes mellitus insulin secretion reduced over a period of time and glucose level is maintained for a period of time by hyperinsulinaemia and but the B cell function is detoriate finally and leads to hyperglycemia. At the time of diagnose most of the patients may have lost 50% of the B cell function continue to detoriate with time, often leading to the need of insulin therapy.

Insulin resistance in cells are increased when the abdominal fats are increased , abdominal fat resistant to the antilipolytic effect of insulin, leads to more free fatty acid release, which cause for insulin resistance in the liver and muscle. The increased glucose production in liver and inhibition of insulin mediated glucose uptake in the muscle result in increased level of glucose in body²⁰ .

COMPLICATION

Long –term complications of diabetes develop gradually. The longer you have diabetes and the less controlled your blood sugar the higher the risk of complications. Eventually, diabetes complications may be disabling or even life – threatening. Possible complications include²¹.

Acute Problems:

1. Diabetic ketoacidosis
2. Hypoglycemia

Chronic complications:

1. Micro vascular complications
 - Diabetic retinopathy
 - Diabetic neuropathy
 - Diabetic nephropathy
 - Diabetic foot
2. Macro vascular complications
 - Peripheral vascular disease, coronary artery disease
 - Myocardial infarction
 - Hypertension and cerebrovascular diseases²².

MICRO VASCULAR COMPLICATION

There are three main micro vascular complications of diabetes

- Diabetic retinopathy
- Diabetic neuropathy
- Diabetic nephropathy

DIABETIC RETINOPATHY

Diabetes can damage the blood vessels of the retina (diabetic retinopathy), potentially leading to blindness. Diabetes also increases the risk of other serious vision conditions, such as cataracts and glaucoma.

DIABETIC NEUROPATHY

Abnormal and decreased sensation, usually in a 'glove and stocking' distribution starting with the feet but potentially in other nerves, later often fingers and hands. When combined with the damaged blood vessels this can lead to diabetic foot. Other form of

diabetic neuropathy may present as mononeuritis or autonomic neuropathy. Diabetic amyotrophy is muscle weakness due to neuropathy.

DIABETIC NEPHEROPATHY

Damage to the kidney which can lead to chronic renal failure, eventually requiring dialysis. Diabetes mellitus is the most common cause of adult kidney failure worldwide in the developed world²³.

MACROVASCULAR COMPLICATION

Macro vascular complications are disease and conditions of the large blood vessels and can occur in blood vessels in any part of the body as a result of diabetes.

There are 3 main macro vascular complications

- Cardiovascular disease
- Cerebrovascular disease
- Peripheral vascular disease

CARDIOVASCULAR DISEASE

People with diabetes are 2-4 times more likely to develop cardiovascular disease [CVD] than those without diabetes. However, the risk of coronary artery disease is increased in patients with poor glycemic control. Additional mechanisms that contribute to the increased risk of CHD and worse outcomes in persons with diabetes include endothelial dysfunction, hypercoagulability, impaired fibrinolysis, platelet hyperaggregability, oxidative stress, sympathovagal imbalance, and glucose toxicity.

CEREBROVASCULAR DISEASE

Cerebrovascular disease term encompassing many disorders that affect the blood vessels of the central nervous system. These disorders result from either inadequate blood

flow to the brain [i.e, cerebral ischemia] or from hemorrhages into the parenchyma or subarachnoid space of the central nervous system [CNS]. Cerebrovascular disease also results in stroke. Diabetes is an independent risk factor across all ages for stroke.

PERIPHERAL VASCULAR DISEASE

Peripheral arterial disease [PAD] is an atherosclerotic occlusive disease. It is the major risk factor for lower extremity amputations. The risk of development of PAD increases threefold in patients with diabetes mellitus²⁴.

TESTS AND DIAGNOSIS

GLYCATEDHEAMOGLOBIN (A) TEST [HBA1C]

This blood test indicates your average blood sugar level for the past two to three months. It measures the percentage of blood sugar attached to hemoglobin, the oxygen-carrying protein in red blood cells. The higher your sugar levels, the more hemoglobin you'll have with sugar attached. An A1C level of 6.5 percent or higher on two separate tests indicates you have diabetes. A results between 5.7 and 6.4 percent is considered prediabetes, which indicates a high risk of developing diabetes.. Normal levels are below 5.7 percent

Poorly controlled patients = 8-20%

In non – diabetic patients = 3 – 6.5%

RANDOM BLOOD SUGAR TEST [RBS]

A blood sample will be taken at a random time. Blood sugar values are expressed in milligrams per deciliter (mg/dL) or mill moles per liter (mmol/L). Regardless of when you last ate, a random blood sugar level of 200 mg/dL (11.1 mmol/L) or higher suggests diabetes, especially when coupled with any of the signs and symptoms of diabetes, such as frequent urination and extreme thirst. A level between 140 mg/dL (7.8 mmol/L) and

199 mg/dL (11.0 mmol/L) is considered prediabetes, which puts you at greater risk of developing diabetes. A blood sugar level less than 140 mg/dL (7.8 mmol/L) is normal.

FASTING BLOOD SUGAR TEST

A blood sample will be taken after an overnight fast. A fasting blood sugar level less than 100 mg/dL (5.6 mmol/L) is normal. A fasting blood sugar level from 100 to 125 mg/dL (5.6 to 6.9 mmol/L) is considered prediabetes. If it's 126 mg/dL (7 mmol/dL) or higher on two separate tests, you have diabetes.

ORAL GLUCOSE TOLERANCE TEST

For this test, which is rarely used anymore, you fast overnight, and the fasting blood sugar level is measured. Then you drink a sugary liquid, and blood sugar levels are tested periodically for the next two hours. A blood sugar level less than 140 mg/dL (7.8 mmol/L) is normal. A reading of more than 200 mg/dL (11.1 mmol/L) after two hours indicates diabetes. A reading between 140 and 199 mg/dL (7.8 mmol/L and 11.0 mmol/L) indicates prediabetes²⁵.

MANAGEMENT OF DIABETES MELLITUS

For the management of diabetes mellitus lifestyle modification is necessary along with pharmacological treatment

NON PHARMACOLOGICAL TREATMENT

Diet Control :Avoid carbohydrates, sugar, reduction of salt intake Include More fiber containing food, vegetables, and fish oils.

Moderate Exercise Include brisk walking, cycling Restrict alcohol consumption Avoid stress, avoid smoking

PHARMACOLOGICAL TREATMENT

The treatment option for type 1 diabetes is insulin. Exogenous insulin are Used control blood sugar level.

INSULIN PREPARATION

Rapid-acting: Onset 5-15 min, Duration 4 hrs.

Lispro
Aspart

Short-acting: Onset 30-60 min, Duration 6-8 hrs.

Regular

Intermediate-acting: Onset 1-2 hrs. Duration 10-16 hrs.

NPH

Long-acting: Onset 2-4 hrs. Duration 20-24 hrs.

Larine
Detemir

Pre-mixed: Onset 30-60 min, Duration 10-16 hrs.

30%/70% regular/NPH

50%/50% regular/NPH

ORAL HYPOGLYCEMIC AGENTS

In type 2 diabetes glycemic control cannot be achieved by only life style modification, along with pharmacological treatment also necessary to control blood sugar level. These agents are used as a mono therapy or combination therapy for the treatment of type 2 diabetes.

(1)SULPHONYLUREAS

Sulphonylureas are a class of oral (tablet) medications control blood sugar levels in patients with type 2 diabetes by stimulating the production of insulin in the pancreas and increasing the effectiveness of insulin in the body²⁶.

Example :Glibenelamide, Gliclazide, Glimepiride

Adverse effects : Hypoglycemia, weight gain

(2)BIGUANIDES

Biguanides lower blood sugar by:decreasing the amount of sugar producing by the liver.increasing the amount of sugar absorbed by muscle cells.decreasing the body need for insulin²⁷.

Examples : Metformin

Adverse effects: lactic acidosis, abdominal discomfort, diarrhea, Vitamin B12 deficiency.

(3) A GLUCOSIDASE INHIBITORS

Alpha –glucosidase inhibitor : A class of oral medications for type 2 diabetes that decrease the absorption of carbohydrates from the intestine,resulting in a slower and lower rise in blood glucose²⁸.

Example :Acarbose, Voglibose, Miglitol

Adverse effects : Hypoglycemia , anemia

(4) THIAZOLIDINEDIONES

These drugs bind to PPAR-γ and change insulin dependent gene expression in the liver. These drugs increase the effect of insulin in skeletal muscle, adipose and hepatic tissues without enhancing pancreatic secretion of insulin²⁹

Examples : Rosiglitazone, Pioglitazone

Adverse effects : Water retention , weight gain

(5)MEGLITINIDES

These drugs bind to ATP sensitive potassium channels and enhance the release of insulin from pancreatic cells, it decrease insulin levels and enhance insulin sensitivity in cells³⁰

Examples :Rapaglinidde, Nateglinide

Adverse effects : Weight gain , hypoglycemia

(6) DIPEPTIDYL PEPTIDASE FOUR INHIBITORS

These drugs enhance the effect of GLP-1 and GIP, and increase glucose mediated insulin secretion and suppresses glucagon secretion, these drugs mostly commonly used as a combination therapy with metformin or TZDs

Examples :Sitagliptin , Vildagliptin

Adverse effects :Upper respiratory infections

If the glycemic control cannot be controlled by monotherapy, then combination therapy is used. If combination therapy is fail to control glucose level, and then insulin therapy is started³¹ .



AIM AND OBJECTIVES

AIM AND OBJECTIVE

AIM

The aim of this study is to determine the different prescribe patterns of medications prescribed by different endocrinologist in treatment of diabetes type 2 mellitus patients and to propose possible interventions.

OBJECTIVE

- ❖ To study the prescribing patterns of the drugs used in the management of diabetes type 2 mellitus at study site ,government hospital at tirupur.
- ❖ To obtain the information on demographic characteristic of the patient selected for analysis.
- ❖ Collect information on the diagnosis, number of drugs prescribed.
- ❖ Analyze the prescriptions for diagnosis, name,dose and duration of prescribed drugs.
- ❖ To assess the diagnosing methods.
- ❖ Observe the entire prescription.
- ❖ To determine attitudes of the physician regarding anti-diabetic drugs prescribing pattern.
- ❖ To assess the use of effective anti-diabetic drugs.
- ❖ To establish the most commonly or drug of choice for diabetes type 2 mellitus patient.



PLAN OF WORK

PLAN OF WORK

The present dissertation work was planned to conduct a prospective cross sectional study to determine prescription patterns of medicine used in treatment of patients with type 2 diabetes mellitus. The present study was conducted in government hospital at tirupur . Patient diagnosed with type 2 diabetes mellitus with or without co-morbidities were enrolled in the study considering the inclusion and exclusion criteria. Informed consent was taken from patient at the time of enrolment in to study.

The plan of work includes:

- ❖ To get oral or written consent from patient.
- ❖ To design data collection form.
- ❖ Select and identify only outpatient s type 2 diabetes mellitus.
- ❖ To evaluate collected data.
- ❖ Data analysis was done with the help of computer(Microsoft excel 2007).



REVIEW OF LITERATURE

REVIEW OF LITERATURE

H.B, Matalia,et al.,(2011). Conducted a study to find out the trend in the prescription of antidiabetic medication among in patient with type 2 diabetes. The study included 130 patients who had diabetes, of either sex and age. Data was analysed using spss 13.0 student's t-test and analysis of variance (ANOVA) was employed to compare quantitative variable and the chi-square test was applied to compare categorical variables. The result indicates that 58.46% was male patient out of which 55.26% were having history of either smoking or alcohol. The prevalence of diabetes was observed more in the population taking non-vegetarian diet. Common disease associated with diabetes mellitus was hypertension (45.38%). Highest prevalence of disease was found in the age between 51 to 60 years (28.46%). Highest prescribed antidiabetic agent was insulin followed by metformin and then glimepiride. In combination. The study indicated that the choice of antidiabetic drug remained more or less unchanged compared to previous studies. The study also revealed the common use of metformin and glimepiride along with insulin treatment for in-patients. The study provides baseline data for carrying out further therapeutic audit with more parameter of analysis which in turn will provide regular feedback to researchers and prescribers. This will encourage rational prescribing in type 2 diabetes mellitus.³²

Mohammad ShamshirAlam, et al.,(2014). Conducted a study to as certain patterns of prescription of oral hypoglycemic agents to type 2 diabetic patients compliance. A prospective observational and non-comparative study was conducted in 200 established diabetes mellitus type 2 patients. Prescription from registered patients was also included in the study. Once the consultation by physician was over the prescription were reviewed and patient interviewed. The information was collected in house designed documentation proforma. In pool of 200 type 2 diabetic more than a half

were female(n=106,53%) the mean age of patient was found to be 50.4+11.7 year and mean body mass index was 25.8+4.4kg/m².A total of 432 oral hypoglycemic were prescribed. Highly significant Number of patient were prescribed with combination therapy.(n=143,71.5%)as compared to monotherapy(n=57,28.5%),p-value 0.0001. Biguanides were the most prescribed followed by sulphonylurea, thiazolidinediones and alpha glucosidase inhibitor. Good compliance was seen only 77.5% patients. Metformin was found to be most prescribed medication.³³

Bela Patel, et al.,(2013).A prospective, cross-section study was carried out in medicine outpatient clinical of tertiary care hospital, patient with type 2 diabetes and on drug therapy for at least one month were included. Patients socio demographic and clinical data were noted in pre-designed proforma. Data was analysed by using SPSS version 20 and excel 2007. Total number of 114 patient were enrolled with mean (+SD) age and duration of 56.8+10.5 and 8.3+9.4 year respectively. Male : Female ratio was 0.721:1 mean fasting and postprandial blood glucose level were 147.5+73.1 and 215.6+97.3 mg/dl respectively. Most common symptom was weak/fatigue (77.2%). Hypertension (70.2%) was most co-morbid illness. Mean number of drug were 89.5 % most commonly used drug group was biguanides (87.7%) followed by sulphonylureas (68.34%). Metformin was the most utilized (87.7%) antidiabetic drug for type 2 Diabetes. This study revealed that the pattern of antidiabetic prescription was rational and largely compliant with NICE guidelines.³⁴

Rajkumar, et al., (2013). In this study 366 prescription slip were randomly collected from outpatient diabetic patients for analysis and evaluation. Average number of drugs prescribed is 4.98. the most commonly prescribed drugs were oral antidiabetic drugs, CVS related (antihypertensive, nitrates, antiplatelet, e.t.c) vitamin and mineral insulin, GIT, related drugs, lipid lowering drugs, antimicrobial, CNS related and NSAIDs and their percentages were 20.55%, 26.97%, 22.20%, 7.8%, 6.5%,5.75%,2.63% and

1.48% respectively. All the drugs were prescribed by non – generic names, which included 31.36% drug from essential drug list. Oral forms prescribed were 85.85% and injectable were 14.15%(insulin 7.8% and other injectable 6.35%). The average cost of oral antidiabetic agent per day prescription was 7.95/- and this cost increased to 10.15/- with addition of CVS related drugs, 17.23/- with vitamin and minerals and 10.57/- with lipid lowering agents and it was seen that if patient prescribed all these drugs then the average cost of treatment got raised to 45/-per day per prescription. There is high tendency and frequency to prescribe more than two drugs but less used from essential drugs prescribed were cardiovascular related drugs and multivitamins along with oral antidiabetic drugs. There is an urgent need to develop the prescription writing skills for budding doctors regarding the use of essential drugs List to reduce the cost of treatment.³⁵

Maguire,et al.,(2014). Conducted a retrospective using primary care data. The objective of this study was to find out determinants of the initial treatment change following initiation on non-insulin antihyperglycaemic treatment (OAD) for UK patients with diabetes with type 2 diabetes. Each patient had OAD prescription. The main treatment pattern out comes were discontinued switching augmentation and initiation of insulin. Glycaemic control was assessed using HbA1c.63060 patient initiated OAD therapy 2006-2010 and 3.4% were prescribed insulin during follow-up.26% with at least four years of follow-up remained in initial treatment. Metformin dominated 90%. Around 75% had record HbA1c value >65mmol/mol and one quarter >80mmol/mol. The initial value reduced after 12 months and remained stable. There were 15-18% of whose value increased since initiating OAD. Increased baseline HbA1c is associated with increase chances of augmentation and decrease chance of discontinuation. HbA1c value at one year is associated three-fold increase in the chance of augmentation, 130% increase in chance of switching and 14 % increase in chance of discontinuation with each 10mmol/mol. Following initiation of OAD HbA1c was reduced by an average of 16mmol/mol in the first year. It was out that there are patient for whom glycaemic control

worsens and majority remained above the recommended level suggesting an unmet need despite the availability of many OAD.³⁶

Richard W.Grant, et al.,(2007). Conducted a study to find prevalence and treatment of low HDL cholesterol patient with type 2 diabetes. Patient with type 2 diabetes remain high risk of cardiovascular event despite aggressive blood pressure, LDL cholesterol and blood glucose control. A total of 7692 patient with type 2 diabetic were analysed. He grouped fibrate niacin and n-3 fatty acid preparation as nonstatin HDL Cholesterol-raising medicines. It was find out nearly 49.5% of patient had low HDL cholesterol (>40mg/dl for men > 50 mg/dl for women). Low HDL cholestereol was prevalently associated with cardiovascular disease, younger age, and higher A/C level nearly two third of the patient 63.8% were prescribed a statin. In contrast only 7.9% patient were prescribed a nonstation HDL cholesterol – raising medicines. It was find out nearly 49.5% of patient had low HDL cholesterol (>40mg/dl for men > 50mg/dl for women). Low HDL cholesterol was prevalently associated with cardiovascular diseases, younger age, and higher A/C level nearly two third of the patient 6.8% were prescribed a statin. In contrast only 7.9% patient were prescribed a nonstatin HDL cholesterol-raising medication including 16.4% of patient below the HDL cholesterol goal with CVD Based on the studies normalizing low HDL cholesterol in primary care cohort would correspond to estimated CVD mortality reduction of 42% in women and 23% in men. Nearly half of this patient in this study had low HDL cholesterol level. In contrast to frequent to statin use, few patients were prescribed with currently available medicine to raise HDL cholesterol level. Low HDL cholesterol represents highly prevalent and potentially modifiable risk foe CVD prevention in type 2 diabetes.³⁷

Chung-Yu Huang et al.,(2013). Conducted a study to analyze the utilization traditional Chinese medicine (TCM) among type 2 diabetic patient when given as a therapy. The use of TCM for type 2 diabetic patient were evaluated using randomly sample cohort of 1,000,000 beneficiaries. 77.9%(n+31,289) of type 2 diabetic patient utilized TCM and 13.9%(n+, .351) of them used it for treatment of the disease. Among the top ten most frequently prescribed herbal formulae, four remedies, Zhi-bo-Di-Haung-wan, Qi-Ju-Di-Haung-Wan, Ji Sheng – Shen-Qi-Wan, Ba-Wei-Di-Haung-Wan. Although some evidence doesn't support the use of this herbals the result from the current study may have been confounded by placebo effect, which emphasize the need of well conducted, double blind, andomized, placebo-controlled studies in order to further evaluate the Liu-Wan-Di-Haung-Wan on patient with type 2 diabetes.³⁸

Roland NneamekaOkoro et al., (2012). Conducted a study to assess the patient's antidiabetic medication adherence levels in non-comorbid diabetes mellitus to identify and to evaluate the cause of medication non adherence. Randomly sampled 72 outpatients suffering from non-comorbid diabetes mellitus. Patient was interviewed using self-administered pre-structured mostly closed ended questionnaires. Adherence was measured on a 12-point scale using variation of the Morisky-Green Test; an adherence means (+_SD) score of 9.0+_1.0 was recorded. The study participants had a mean(+_SD) age of 48.0+_11.7 year majority were females 65.3% and married 77.8%. The adherence levels were 1.4%, 25%, 13.9% and 59.7% for neutral, poor, medium, and good adherence respectively. There was a significant association between gender and levels with $p > 0.01$. Most common for non-adherence to taking medication as prescribed were feeling better (40%), feeling worse due to side effect of anti-daibetic medication (65%). The nature of work and busy work schedule (43%) and long wait time at the clinic (29%) were responsible for non adherence to clinic appointments. The majority of participants that sometimes missed doses of their medication took them as soon they remembered when time of the next dose was far and skipped them when the time to the next dose was close.

In conclusion, the study revealed a moderate level of good adherence among the participants.³⁹

DhwaniKamrai,et al.,(2010) The study was conducted with the objective of providing insight in to current use of antidiabetic medication to diabetic and hypertensive diabetic and determine how the patient factor influence the prescribing of antidiabetic medication. A retrospective epidemiological study was performed using out patient data. Data of patient profile form. Data were statistically analysed using SPSS software. A total of 492 patients were involved out of which 67.88% were male and 32.11% were female. They were further categorized in to age 25.6% belonged to the age group of 65-80 years. 50% of patient out of 492 studied were suffering from co-existing hypertension. Co-existence hypertension was found to be more prevalent in the age group 45-65 years.59.75% and its incidence was found to be more in female. Metformin was highly prescribed. Metformin and Acarbose were given to obese patient. Sulphonylureas and thiazolidinedione were prescribed less. In hypertensive diabetic metformin and pioglitazone were mostly prescribed drugs. Monotherapy was prescribed for 11.3% patient and remaining patient were prescribed with combination therapy. Biguanides and insulin were the mostly prescribed antidiabetics. Since the scope of the study is limited to number of patient studies it is less extensive as required to confirm studies are required to confirm the findings.⁴⁰

ManjiriPawaskar, et al., (2013). Conducted study to evaluate medication utilization in patient with type 2 diabetes mellitus treated with exenatide BID (exenatide) versus insulin glargine (glargine). In the study adult patient(>_ 8 years of age) with type 2 diabetes who were initiator of excenatide or glargine were selected. To control for selection bais, propensity score matching was used to complete a 1:1 match of glargine to exenatide patients. A total of 9,197 exenatide and 4,499 glargine treated were selected. Propensity score matching resulted in 3,774 match pairs with mean age of 57 and mean

age DeyoCharlson comorbidity index score of 1.6;54% patient were male. The treatment intensification rates were 15.9% and 26.0% ($p<0.0001$) and discontinuation rate were 38.3% and 40% ($p=0.14$) for exenatide and glargine respectively. Alternatively 14.9% of exenatide treated patients switched their therapies compared to 10% glargine treated patients ($p>0.0001$). Overall, glargine treated patient were likely to modify their treatment with shorter mean time on treatment until modification. Compared to exenatide treated patients, glargine treated patient were likely to discontinue or intensify therapy. But likely to switch the index therapy. Patient treated for type 2 diabetes with exenatide BID or insulin glargine differ in adherence to therapy.⁴¹

Ibrahim A.Ibrahim, et al.,(2008). Conducted the study to examine the drug regimens diabetic patient receiving home health care service to measure the prevalence of polypharmacy and to assess likelihood of drug- drug interaction and the consequence. The study consisted 139 patients. Information regarding medication was collected by home health nurse during the initial home visit and was recorded in patient medication sheet. Any change in medication was noted. All systemic medication prescribed were identified. Micromedex formulary DRUG-REAX SYSTEM was used to identify drug- drug interaction. It was found that average number of medication taken was 8.9(SD 3.4) prescribed medication per day. The show that 38.8% of patients in the sample could potentially subjected to at least one severe drug- drug interaction. Nearly all the patient (92.8%) were at risk of moderate drug- drug interaction, and 70.5% would have mild drug- drug interaction. It was concluded that polypharmacy is concern for home health care patients with diabetes and potential drug-drug interaction is substantial. Result indicates to avoid adverse events such hospitalization.⁴²

YahayaHassan,et al.,(2009). Conducted a study to identify trend of in utilization of oral hypoglycemic agent (OHA) in effort to expand the existing knowledge and to describe changes observed. Prescription records were retrospectively reviewed in the

outpatient department. About 12,000 prescriptions containing at least one OHA were systematically sampled and evaluated. Chinese Patients had decreasing trend in OHA with decreasing trend usage over time (52.2% to 48.5%). In contrast metformin Biguanides agents, recorded an increase in utilization over the study period, Suggesting a new trend for prescribing practices among medicalpractitioner (48.6% to 51.3%;p-value<0.001). Although monotherapy was popular with metformin overall pattern profound favoured combination therapy. This study also found an increasing pattern in the use OHA with insulin rather than triple OHA therapy among practitioners. The Biguanides is gradually becoming a new reigning lord of OHA replacing sulphonylureas. Pattern of OHA use is shifting towards combination therapy mainly dual OHA therapy and OHA-insulin therapy.⁴³

Mohammad Yasmeen Abbasid, et al., (2014). Conducted a prospective observational study for a period of six month in Inpatient department. Patient of either sex age \geq 8 years and above, patients who were diagnosed as diabetic were included in the study. A total of 133 patients were recruited for study,61% of the patients were male, and 39% were female. Most of the patients were age group 51-65(44.36%).70.67% had no family history of diabetes,59.33% of patient had family history. The major comorbidities was hypertension (43.64%) followed by hyperlipidaemia (17.67%). The total prescribed antidiabetic medication was 31.58%. Among the antidiabetic drug given Metformin was the most prescribed 35.26% followed by sulphonylureas 30.65% then insulin 21.96% thiazolidiones 9.12%, and DPP-4 Inhibitor 1.65%. It was find out prescribing pattern of drug should be based on the severity of disease condition,Associated comorbid and currently available evidence in order to promote quality use of drugs.⁴⁴

HarikrishnanK.V,et al.,(2012)Conducted observational prospective study to find prescription pattern and insulin treatment in diabetic patients. The study also included the

patient analysis of patient information and comorbid condition. The objective was to determine the Patient information, prescription pattern and treatment of type DM using insulin. Patient information such as MRD no, sex, age, duration of hospital stay, comorbid condition, patient profile information and details of insulin treatment were collected. In total 50 patients were used, 72% were male and 28% were female. From the medication profile of the patient it was found that 43 patient are treated with insulin. It is observed from the study insulin is commonly used in all type 2 diabetes mellitus patient. Human mixtard and human atrapid are two common classes of insulin which is used for treatment.⁴⁵

K U Denish, et al., (2007). Conducted a prospective study to identify and analyze pattern of potential DDIs (drug-drug interaction) in diabetes patient. A total of 182 patients were prescribed 685 drugs were enrolled. Patient 51 to 60 age had higher risk developing DDIs. It was found that of DDIs 49.5%. The common potential DDIs observed was between metformin and enalapril.⁴⁶

BalazsHanko, et al., (2002). Conducted a study to evaluate the utilization of antidiabetic drugs. The consumption of antidiabetic drugs was analyzed by the ATC/Defined Daily dose (DDD) method. The total consumption of antidiabetics increased by 41.8%, and reached 47.59 DDD/1000 inhabitant/day. The consumption of oral antidiabetic increased by 33.41% (DDD/1000 inhabitant/day) while in the case insulin was 67.8% (13.74 DDD/1000 inhabitant/day) sulphonylureas were most frequently used class. Glibenclamide was the most frequently used antidiabetic drug. The insulin class had greater emphasis in therapy. Among oral antidiabetic, the consumption rate of sulphonylureas decreased and the consumption rate of biguanids and acarbose increased.⁴⁷

VitthalKuchake, et al., (2010). Conducted a study to evaluate the prescribing pattern of antidiabetic and compare serum lipid profile in diabetic patient. 163 patient were enrolled in the study. Fasting serum lipid profile was analyzed. Antidiabetic medication were evaluated in selected the study population for prescribing pattern of drug and their cost evaluation. Among various antidiabetics, Biguanides were mostly prescribed. Most the study subjects had lipid abnormalities and there was statistically difference in the proportional of subject with different BMI category and lipid abnormalities. Significant increase in level serum cholesterol ($p < 0.01$) and serum LDL-C ($p < 0.0001$) and significant decrease HDL-C ($p < 0.0001$) in over weight subject was observed. Metformin was the commonly prescribed. Elevated LDL-C and serum cholesterol and reduce HDL-C are prevalent lipid abnormalitiles in diabetic mellitus patient.⁴⁸

Giorgio L Colomb,et al., (2012).Conducted the study to evaluate the use of antidiabetic with particular reference to type of treatment. The analysis was carried out on sample of 169,375 patient treated with oral blood glucose lowering drugs. Patients were considered on treatment with oral blood glucose lowering-drugs if they received at least one prescription of antidiabetic drug. The mean annual number of hospitalizations was lower in the dual therapy group; average number of specialist examination was lower in fixed-combination group. Patient on monotherapy showed a better percentage for glimepiride (70.5%) and pioglitazone(70.4%), whereas the adherence in fixed-combination therapy was recorded for metformin+pioglitazone(75.5%). The average annual cost per diabetic patient was \$2388, with difference between the monotherapy \$2321, fixed-combination \$2270 and dual therapy \$2465 groups. Fixed combination therapy involved a lower mean expenditure for insulin, other drug, and specialist and diagnostic care. Thiazolodinediones showed the lowest average annual cost per patient among the monotherapies, with a marked decrease in cost for hospitalization, specialist care, and diagnostic.⁴⁹

PL De pablos-Velasco, et al., (2005). Conducted a study find out the pattern of hypoglycemic treatment and to estimate the prevalence of known and drug treated diabetes mellitus. A total of 2924 diabetic patient >20 years old were selected. Of the DM-2 patient 4.4% received diet only, oral drugs, insulin or combination. The duration of DM-2 was associated with more oral drug and more insulin treatment, but duration of DM-1 was not associated with intensive insulin therapy; >50% of type 1 patient has >3daily injections. The prescription of Biguanides were scarce, 1/3 of them were buformin. DM-1 and DM-2 patients were treated with similar does of insulin, but DM-1 and DM-2 patients were treated with similar does of insulin, but Dm-1 patient had more insulin injection (2.56 vs 2.07, $p<0.001$). The estimate prevalence of known and drug treated diabetes were 5.95% and 5.73%. The prevalence of known and drug treated diabetes is among the highest reported in European population. The prescription of metformin and combination therapy in DM-2 and of intensive insulin therapy in DM-1 is more intensive and uses more fast-acting insulin than DM-2.⁵⁰

SudhaVengurlekar,et al., (2008). Conducted a study to access prescribing practice and general trend of diabetes among patient. The study revealed that metformin (27%) and glimepiride (22.03) were found maximum among various antidiabetic drug. Category wise the maximum prescribed drugs were glimepiride (22.06%), sulphonylureas metformin (27%,biguannide) and pioglitazone (13.90%, glitazone). Insulin prescription was found to be less (4.5%). Combination of metformin and glimepiride was found to be 20.86% which was prescribed more. Most prevalence of disease was found to be in the age group of 51-60 year old followed by age group of 41 to 50 male patient (66.36%) were found predominant over female(33.64%) patient.⁵¹

Dolores Mino-Leno,et al.,(2005).Conducted study to describe the treatment and outcome in terms of degree of metabolic control in patient, asses the agreement between

the doses of antidiabetic drug by the patient and those written in the medical records, and describe the drug utilization characterization in relation to the standard of care. Consecutive patient with type 2 diabetes were interviewed regarding lifestyle, diet, glycosylated haemoglobin level, and treatment. Concordance between information obtained through medical records and patient interviews was analyzed. Metabolic control was deficient in 40%, acceptable 28%, good in 32% of 181 patients with available information. For 19% patient there was disagreement between the doses of antidiabetic drug reported. For 41% patients, treatment in the medical history was in agreement with published standards. Identification of disagreement between standard of care and clinical identification and clinical practice in type 2 diabetes management is the basis to improve drug utilization and achieve better metabolic control in patient.⁵²

Fredric J.Cohen, et al.,(2003).Conducted study to determine whether antihyperglycemic agent prescribing pattern has changed currently with introduction of new drug, and whether those changes were related to changes in the underlying patient population. A sample of patient with suspected type 2 diabetes was identified. Patient with type 2 diabetes were identified among those continuously enrolled in the database for one year. Drug therapy episode were identified were defined by sequential fulfilment of prescription implying a continuous supply of particular drug (or combination) of at least 30 days duration.Univerariate analyses were used to explore trend over time in drug prescription and patient characteristic. Multivariate logistic regressions were used to isolate the impact of year from other variable on the like hood of receiving prescription for a specific therapy. A total of 232,020 unique diabetic patients had an average of 1.91 diabetes therapy episodes. Monotherapy with sulphonylureas decreased but monotherapy with thiazolidinedione,metformin and other antidiabetic drugs increased over time. Combination of sulphonylureasandmetformin,sulfonylureas and thiazolidinedione, metformin and thiazolidinedione,and sulfonylureas, metformin ,thiazolidinedione increased with time interval. Insulin monotherapy decreased as did

insulin combination therapy with sulfonylureas. The combination of insulin and metformin combination therapy increased, whereas insulin and thiazolidinedione was stable. The influence of year on prescribing patterns remained highly significant ($p > 0.001$) after adjusting for patient characteristics. Antihyperglycemic prescription pattern have changed in recent years in parallel with. And probably as direct a result of introduction of different classes of medication. Overall, The prescribing trend has been away from monotherapy with insulin and sulfonylureas and towards combination therapies, presumably in attempt to reduce hypoglycemic symptoms and achieve better glucose control.⁵³

Kristian B.Filion, et al.,(2009).Conducted a study to describe trend of prescription of antidiabetic medication among type 2 diabetic patient. Using data from general practice Research database they constructed a cohort of patient with type 2 diabetes. Diabetes was defined as the presence of diagnosis of diabetes, HbA1c $> 6.5\%$, and or $> 6.5\%$ prescription for antidiabetic medication. Analyses were conducted for the full of cohort as well as sub-cohort with incident of diabetes. The cohort study included 67981 patients and a total of 320,089 patient-years and the sub cohort had 30,324 patients with incident of diabetes and 111,890 patient-years. From 2000-2006 year there was substantial increase in the prescription rate of antidiabetic medication. The greatest relative increase occurred in the prescription of thiazolidinediones. The greatest absolute increase occurred in the prescription of metformin which surpassed sulfonylureas which was the most prescribed antidiabetic medication among patient with type 2 diabetes 2002. Among those with incident diabetes, overall prescription rate were 4.6% prescription/patient-year 2002 and 13.6 prescription/patient-year 2006. It was found that there was substantial increase between 2002 and 2006 in the UK in the prescription of antidiabetic medication. This increasingly aggressive pharmacology management is consistent with recent practice guidelines.⁵⁴

PremlataDas,et al.,(2009) Conducted an observational follow up in 154 newly diagnosed diabetes mellitus patient. The aim of the study was to determine the demographic, prescribing pattern, drug cost and analysis effectiveness of different therapies. Effectiveness of therapies was analysed in patient achieving glycemic control by Wilcoxon signed rank test. Majority of the patients(n=114) fell in to middle age strata of 35-64 years and 97% were type 2 diabetics. A total of 282 prescriptions were screened that included antidiabetic drugs and drug categories. Mean number of drugs per prescription sheet was 1.83+-1.33. Oral hypoglycemic are advised to 64% patients. The prescribing frequency of biguanides was (24./5%) was more than sulphonylureas (19.9%). Only 67 of the patient followed up to 3 months +_13 days, of which 46 achieved glycemic control. The biguanides only(n=0.002) and combination therapy of biguanides and sulphonylureas group (p=0.005) highly effective therapies, as their p value of fasting blood levels follow up were the lowest. Nearly 90% of combination therapy achieved glycemic control. In conclusion, this study reflects the therapeutic approach followed in diabetes mellitus as optimal. Future research on a larger patient is warranted to evaluate existing pattern of therapy for sound practice and quality of care.⁵⁵

V.Sivasankari,et al., (2013). Conducted study to evaluate utilization pattern of antidiabetic drug in type 2 diabetic DM patient. A prospective observational study was carried out for a period of 6 months. Out of 1456 patient screened, 92 types 2 diabetes were included and structured questionnaire was used to collect data analysis done. The prevalence was about 6.3% and 68.47% of them were 40 to 60 years of age. Hypertension was common co-morbid condition |(19.6%) followed by hypercholesteremia (3.3%). Totally 21.74% of the patient was on monotherapy and metformin was commonly prescribed. In combination therapy, glibenclamide and metformin (35.86%), followed by glimepiride and metformin (9.78%) and injection insulin mixed with metformin (27.17%). Statin was co-administered in 5.5% of patient and there was no evidence of polypharmacy. It was concluded type 2 DM was treated effectively with both insulin and oral hypoglycemic drugs Glimepiride can be substituted by glibenclamide due to better

pharmacological and pharmacokinetic properties. Statins and low ACE inhibitor can added according to recent ADA guidelines to minimize the complication of DM.⁵⁶

ShruthiVihangBrahmbhatt, et al(2014). Conducted a prospective non interventional study aimed to gather and study the drug utilization pattern in diabetic patients. 50 diabetic patients were involved. Patient were included in the study after obtaining written informed consent from, all relevant data was collected from case records froms and analysed. Diabetes mellitus was high in patient with age group 60-70 years, affecting 66% male and 34% female. It was found out metformin is the most used drug with least adverse effects and insulin was used to treat uncontrolled state, where physician have considered the socio-economic status while prescribing which is obvious least use of costly insulin preparation.⁵⁷

Shaktibala Dutta, et al., (2014). Conducted the study to design and analyse current prescriptionmpatterns for drugs used in the treatment of type 2 diabetic mellitus patient. Prescription were randomly evaluated for prescribing pattern using WHO indicators. At total of 312 of prescription were anlysed. Mean age was 54.94+_0.57 years. Male to Female ratio is 1.04:1,socio economic status : upper 24 (7.69%), upper middle 75(240.4%), lower middle 93(29.81%), upper lowr 69(22.11%) and lower 51(16.35%). Family history of diabetes mellitus seen in 129 (41.35%) patient and average duration was 7.92+_0.37 years. A total of antiplatelet 42(3.38%) statin and 360(5.56%) miscellaneous category were prescribed. Amongst antidiabetics, the most frequently prescribed drugs were metformin 273 (40.99%)glimepiride 228(34.23%) then pioglitazone 45(6.67%), acarbose 33(4.95%), gliclazide 30(4.5%), sitagliptin 30(4.5%),glibenclamide 15(2.25%) and insulin 12(1.8%). 99.03% oral drugs were prescribed. Number of fixed dose combinations were of antidiabetic drugs were prescribed. Number of fixed dose combinations were of antidiabetic drugs were 246(36.93%).3.39% drugs per prescription were we prescribed.288(43.24%) antidiabetic

drugs were prescribed from national list of essential medicines (NLEM), 20.11.100% were prescribed by brand names. The most prescribed drugs were metformin glimepiride. Rational prescribing can be improved by sensitizing our physicians and providing them with feedback of study.⁵⁸

Camilo Molino Guidoni, et al.,(2012). Conducted a study to analyse drug prescriptions for insulin and oral antidiabetic drug in type 1 and type 2 diabetes mellitus patient. All patients with diabetes were included in the study. Total of 3982 patient were included. Mean age was 60.6 years and 61% were female. 60% were treated with monotherapy than in polytherapy. Ten patient received doses of glibenclamide or metformin above the recommended maximum doses, and in elderly patient there was no reduction in drug doses. It was out that monotherapy with oral antidiabetic drugs was predominant procedure and the doses were not individualized according to age.⁵⁹

AbdulGafar O. Jimoh, et al.,(2011). Conducted descriptive cross-section study to find out pattern in which drugs are prescribed among diabetic type 2 patients. The study included 496 patient case notes with mean age 46.5+12.5 years. Male to female ratio was 1:1.5. Majority patient were type 2 diabetic (90.3%). The percentage of patient on antidiabetic monotherapy and combination therapy were 28.8 and 75.2 respectively. Of 348 patient on antidiabetic combination therapy 293(84.22%) and 55(15.8%) were 2 and 3 drug respectively. Overall metformin was the most prescribed 81.9%. However as monotherapy metformin was overtaken by insulin as most frequently utilized. Hypertension was the most frequent comorbid condition (43.9%) observed in the study and antihypertensive agents particularly angiotensin converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) monotherapy. The study revealed that the pattern of antidiabetic prescription was rational and largely compliant with clinical guidelines. However, antihypertensive agents was found underutilized for managing patients with both hypertension and diabetes.⁶⁰



PATIENT AND METHODOLOGY

PATIENT & METHODOLOGY

NAME OF THE STUDY

Prescription pattern of medication given in the management of type 2 diabetic mellitus in outpatient department.

STUDY DESIGN

A prospective cross sectional study was performed on 110 patients to know the prescribing patterns of medication used in the treatment of type diabetes mellitus, for six months between July 2017 and March 2018.

STUDY SITE

This study was conducted in the outpatient diabetology department.

DURATION OF STUDY

The study was conducted for six months.

STUDY POPULATION

Patient who visited the diabetic department in government hospital at tirupur were included in this study.

SAMPLE SIZE

A total of 110 patients were enrolled in the study. The patients who had type 2 diabetes mellitus were included in this study.

STUDY CRITERIA

Inclusion Criteria

- ❖ Only prescriptions of patients who are diagnosed to have diabetes type 2 mellitus.
- ❖ Diabetes type 2 mellitus patients with either sex.
- ❖ Patients who were willing to participate in the study.
- ❖ Patients diagnosed with type 2 diabetes mellitus.
- ❖ Out-patient for type 2 diabetes mellitus.

Exclusion Criteria

- ❖ Patients who are not willing to participate in the study.
- ❖ In-patients.
- ❖ Patient who visited for other purpose like renal disease or renal dysfunction with congestive heart failure.



OBSERVATION AND RESULTS

OBSERVATION AND RESULTS**Table 1 : Showing Gender Wise Distribution In Type 2 Diabetes Patient**

Sex	No of Patient	Percentage%
Male	52	47.27%
Female	58	52.73%
Total	110	100

47.27 men and 52.73% women taken for this study.

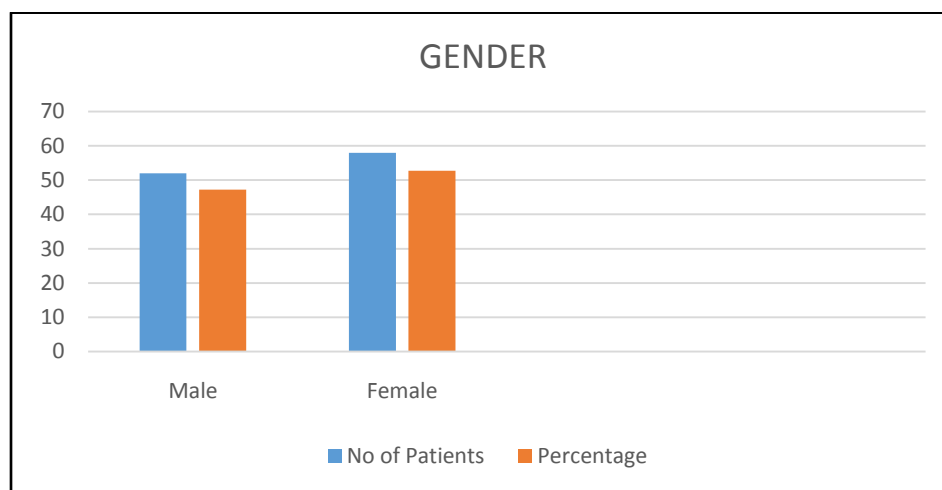
GENDER WISE DISTRIBUTION

Figure 1: Showing percentage of gender wise distribution in type 2 diabetic mellitus.

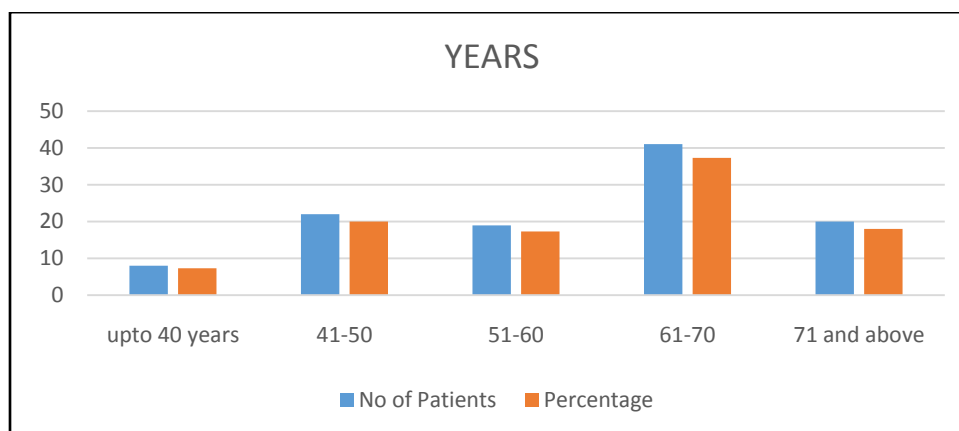
Out of 110 patient 52(47.27%) patient were male and 58(52.73%) were female. According to this male were prevalent to diabetic type 2 mellitus than female patient.

Table 2 : Showing age wise distribution in type 2 diabetes mellitus.

Age Group	No of patient	Percentage
Up to 40 Years	8	7.27%
41-50 years	22	20%
51-60 years	19	17.27%
61-70 years	41	37.27%
71 and above	20	18%
Total	110	100

**Type 2 diabetic mellitus was more prevalent in age group between 61-70
[41(37.27%)] years**

AGE WISE DISTRIBUTION



In this study the revealed that type 2 diabetic mellitus patient was more prevalent in the age group 61-70 years [41(37.27%)] followed by the age group of 51-60 year [19(17.27%)].

**Table 3: Illustrating Details of Drugs prescribed For Patient with Type 2
Diabetic Mellitus**

Drug Name	No of prescription	Frequency (%)
Biguanides	77	70%
Sulphonylureas	64	58.18%
Insulin	32	29.09%
Antiplatelet	10	9.09
Angiotensin receptor blockers	26	20%
Beta-blockers	22	15.71%
Calcium Channel blockers	16	14.54%
Nitrates	7	6.37%
Diuretics	15	13.63%
ACE inhibitor	20	18.18%
Alpha adrenergic	6	5.45%
Proton pump inhibitors	25	22.72%
Antiemetic	10	9.09%
Anti-depressant, anxiolytic	15	13.63%
Antipyretic, analgesic	22	20%
Calcium, Folic acid, Iron	12	10.90%
Antibiotic	27	24.54%

DETAILS OF DRUG PRESCRIBED

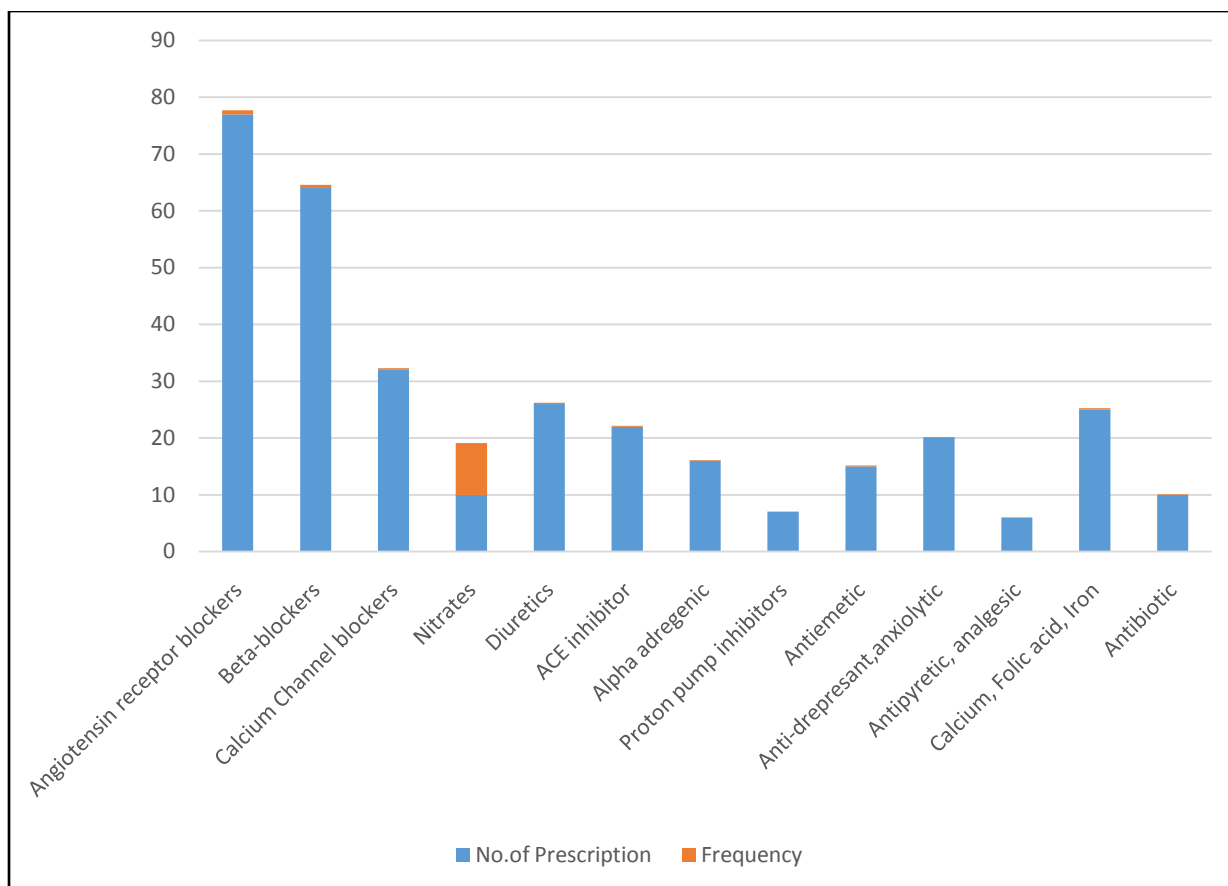


Figure 3 : Illustrates prescribing pattern of drugs in this study population.

Mostly commonly prescribed anti-diabetic drug was Biguanide 70% followed by sulphonylureas 64%, followed by angiotensin receptor blockers 20%

**Table 4 : Monotherapy And Combination Therapy of Antidiabetic Drugs
Prescribed In Type-2 Diabetic Patient**

Drugs	No of Patient	Frequency (%)
Monotherapy	78	70.43%

78(70.43%) type-2 diabetic patient received monotherapy.

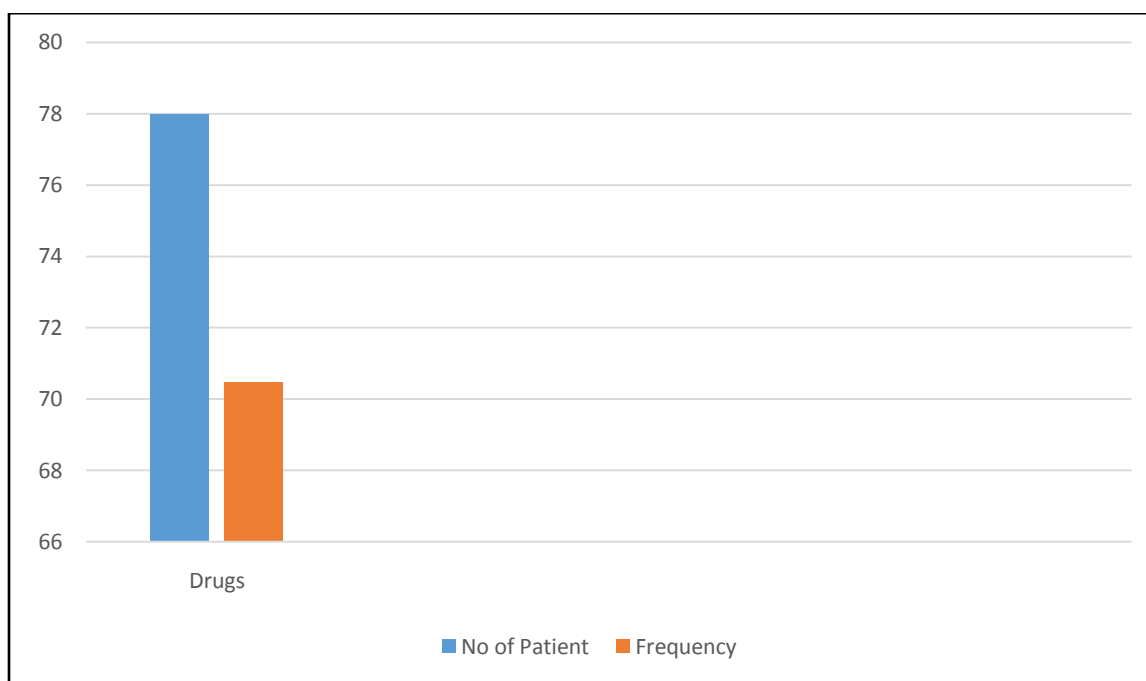


Figure 4: Showing different approach of treatment of type 2 diabetic patient

The study revealed that 70.43% patient were prescribed with monotherapy drug.

Table 5 : Distribution of classes of Anti-Diabetic Drugs Prescribed In Type -2 Diabetic Patient As Monotherapy and Combination Therapy

Drug Groups	Monotherapy(%)
Biguanides	77(70%)
Sulphonylureas	64(58.14%)

Biguanides (metformin) was highly prescribed as monotherapy in (70%) patient

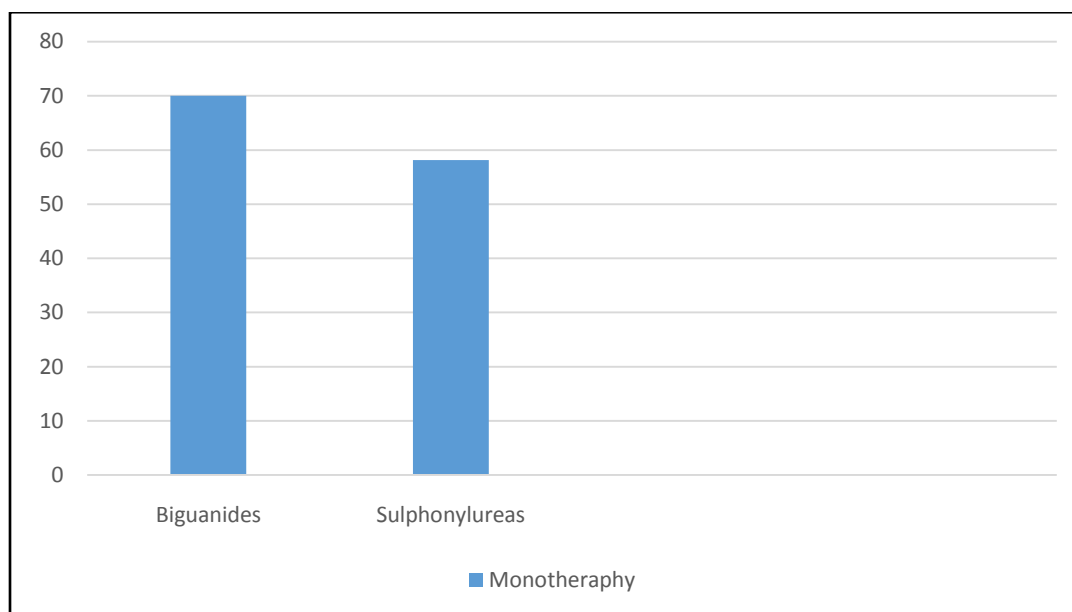


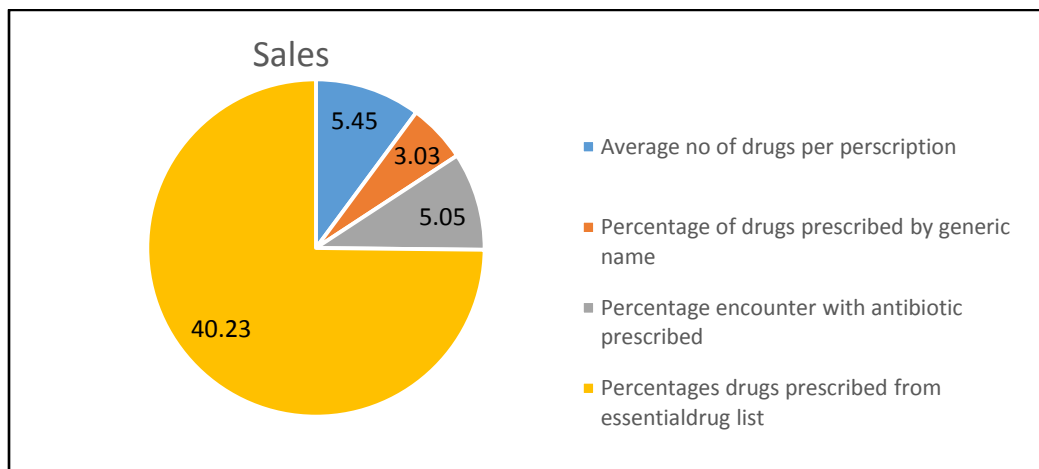
Figure 5 : Distribution of classes of anti-diabetic drugs prescribed in type -2 diabetic patients as monotherapy and combination therapy.

The study revealed that Biguanides was highly distributed as monotherapy (70%) .

Table 6: Who Core drug Prescribing Indicators

Parameter	Value
Average number of drugs per prescription	5.45
Percentage of drugs prescribed by generic name	Nil
Percentage of encounter with an antibiotic prescribed	3.03%
Percentage of encounters with an injection prescribed	5.05%
Percentage of drugs prescribed from essential drug list	40.23%

Average number of drugs prescribed per prescription was 5.45

**Figure 7 : WHO core drug prescribing indicators**

The study revealed that there was no drug prescribed with its generic name, percentage of encounter with antibiotic is 3.03%, the average number of drugs per prescription is 5.45, percentage encounters with an injection was 5.05% and percentage of drugs prescribed from essential drugs list is 40.23%.

Approach of Treatment

- ❖ According to this study more number of patient received monotherapy treatment [78(70.43) .As shown in table 4.
- ❖ In monotherphy the result showed that Biguanide (metformin) [77 (70)] and Sulphonylureas (Glimepride)[64(58.41)] were the least prescribed anti-diabetic drugs. As shown in table 5.
- ❖ In momotherapy, Biguanides was highest prescribed, 77[(70)], followed by Sulphonylureas[64(58.14)].
- ❖ 32(29.09%) of the patient were prescribed with insulin injection. As shown in table 3.



OBSERVATION AND RESULTS

OBSERVATION AND RESULTS**Table 1 : Showing Gender Wise Distribution In Type 2 Diabetes Patient**

Sex	No of Patient	Percentage%
Male	52	47.27%
Female	58	52.73%
Total	110	100

47.27 men and 52.73% women taken for this study.

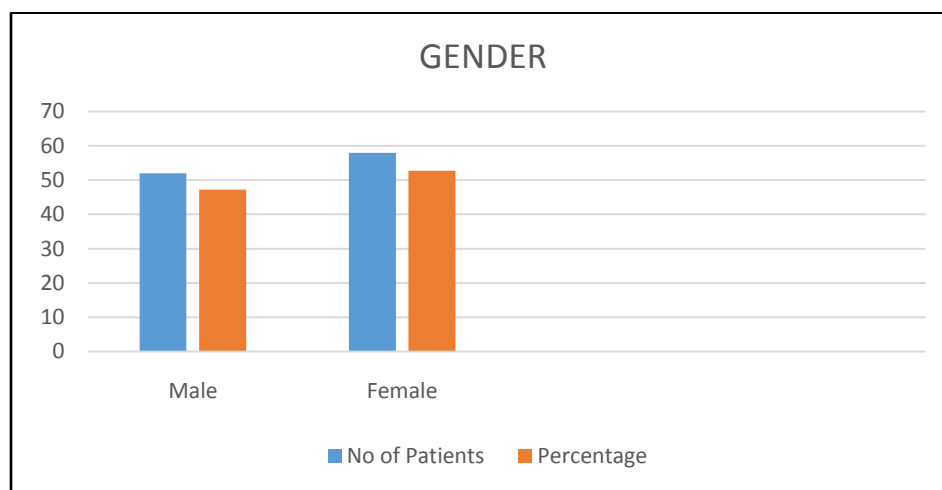
GENDER WISE DISTRIBUTION

Figure 1: Showing percentage of gender wise distribution in type 2 diabetic mellitus.

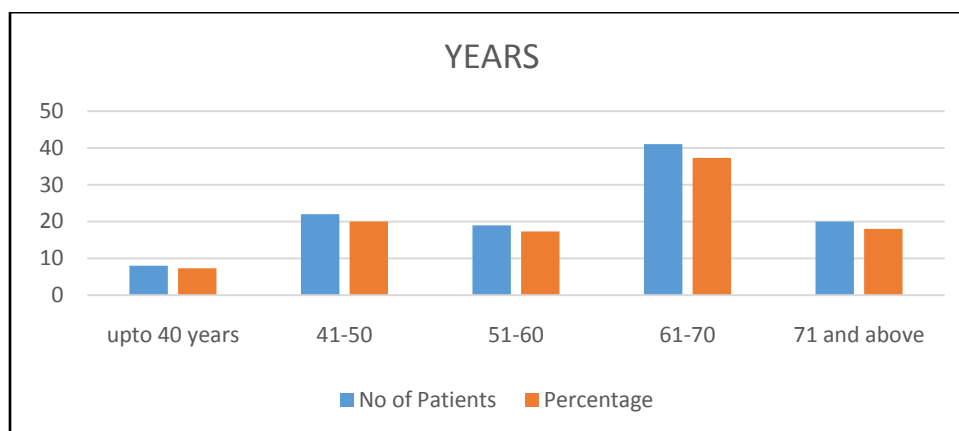
Out of 110 patient 52(47.27%) patient were male and 58(52.73%) were female. According to this male were prevalent to diabetic type 2 mellitus than female patient.

Table 2 : Showing age wise distribution in type 2 diabetes mellitus.

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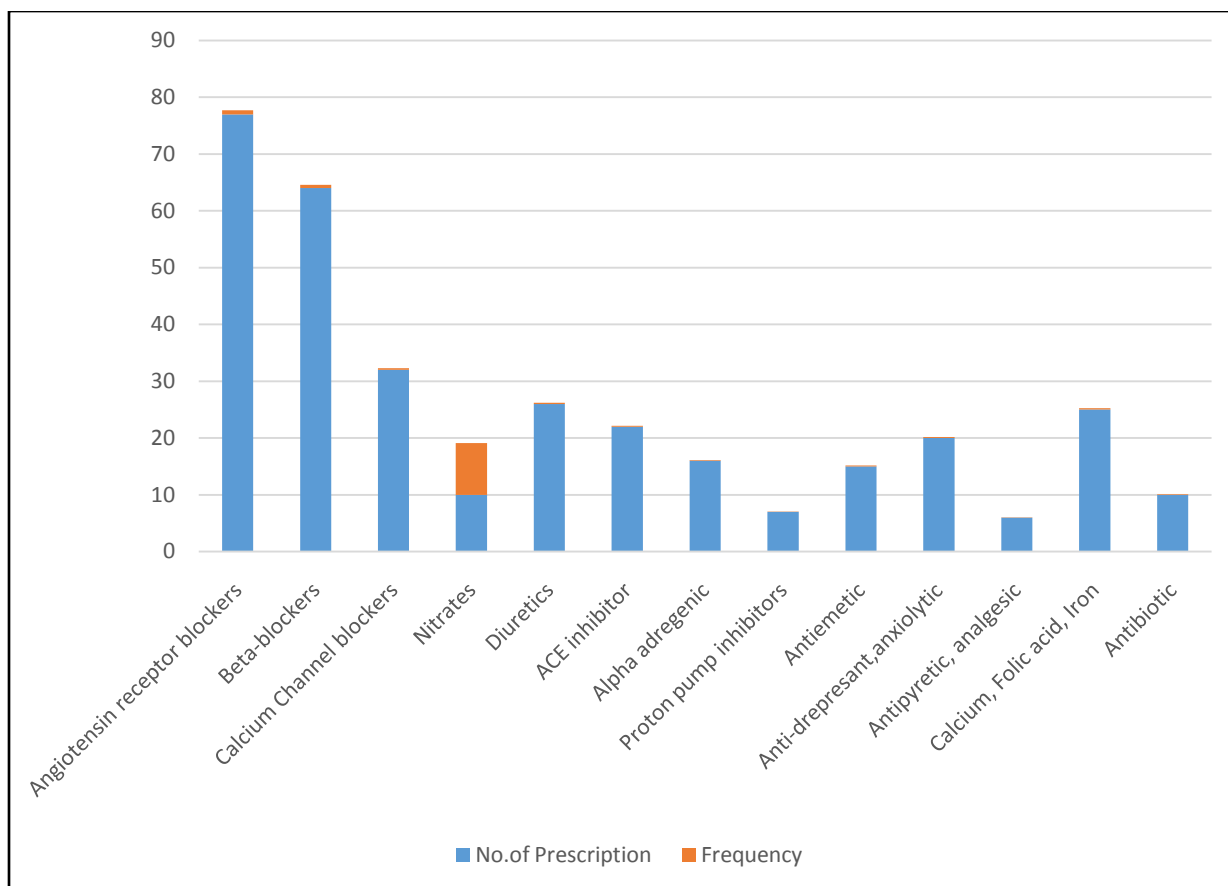


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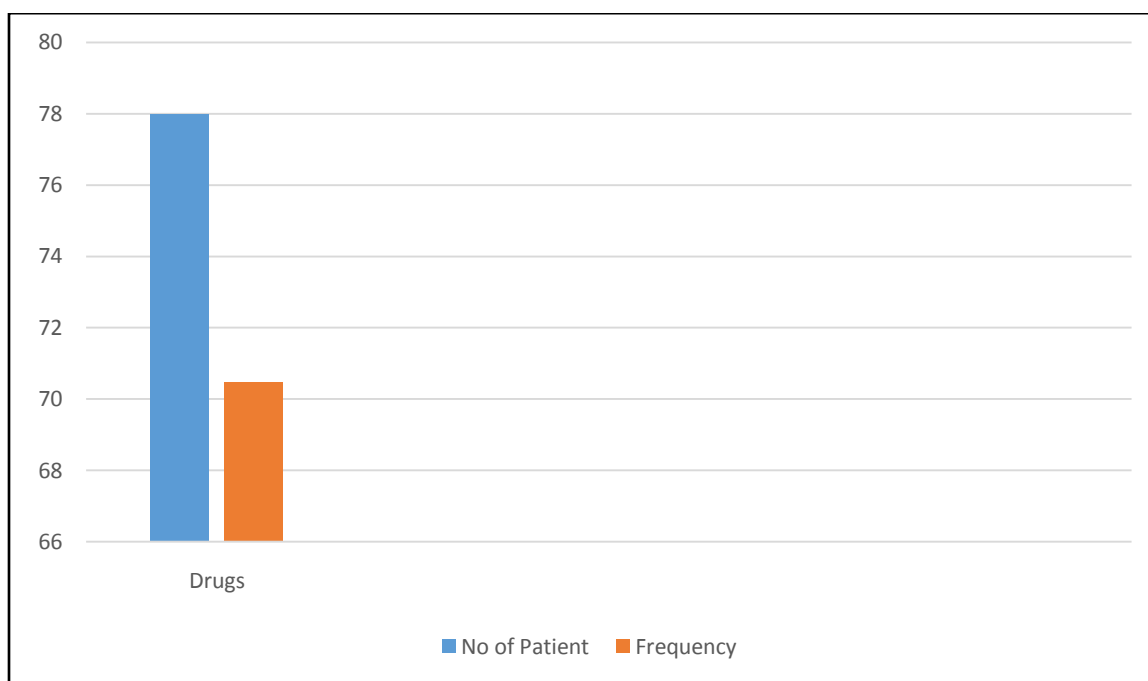


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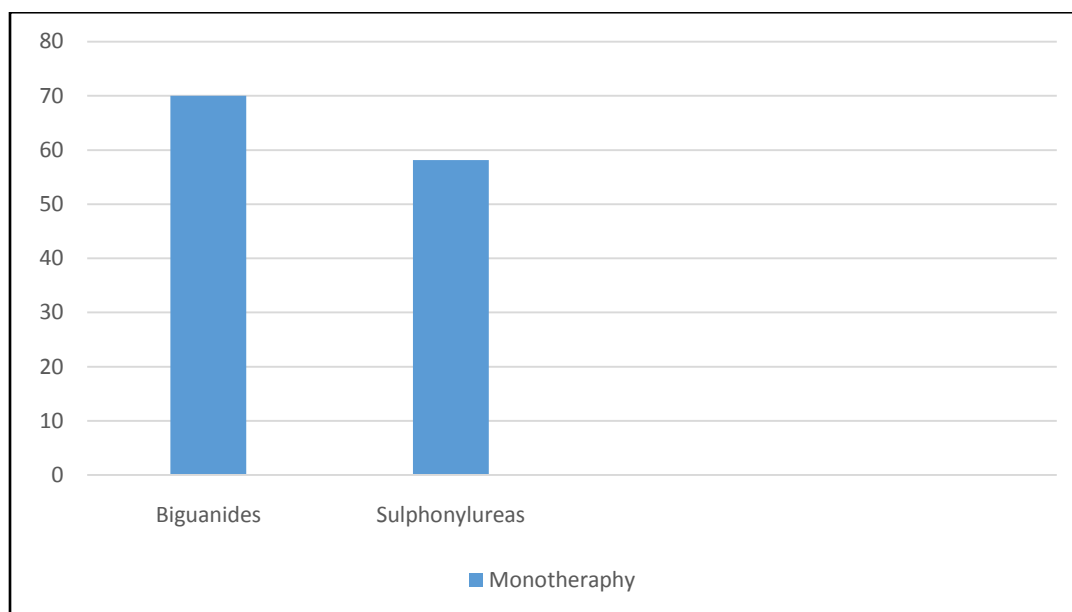


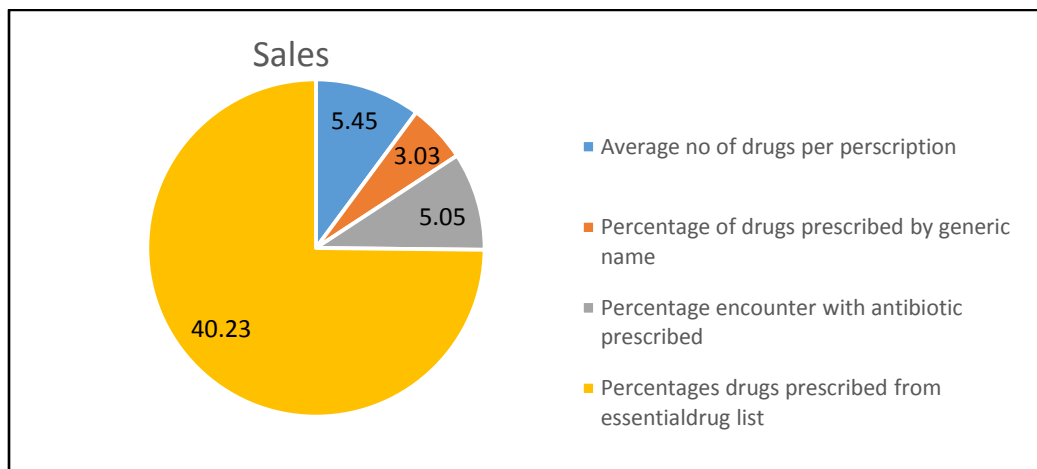
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DISCUSSION

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Diabetes mellitus is a major public health problem worldwide. Its prevalence is rising in many parts of the developing world, India is no exception, currently India is facing a three – fold rise in the prevalence of diabetes, and it will become diabetes capital of the world in near future. Individuals with type-2 diabetes are considered on high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of complication.⁵⁴

In this study we found out patient of age group 61-70 years were most affected by type-2 diabetic mellitus disease, similar to that obtained in other studies. In this study 110 out-patient were enrolled, out of which 52(47.27%) were male patients and 58(52.73%) were female patients. Therefore high proportion of diabetic patients in this study were represented by male similar to the other findings and in contrast to other studies.^{40,}

It was observed some of the 110 enrolled out-patient were suffering from co-morbidity disease such as Hypertension, Hyperlipidaemia, Diabetic retinopathy, Diabetic nephropathy that's why cardiovascular drug were together prescribed along with anti-diabetic drugs. Therefore the average no of drugs prescribed to these outpatients was high due to co-morbid illness of patient in this study, and they required more medication for the additional illness. Different studies also reported the same observation with regard to the co-morbidity in patients with diabetes.⁵⁸

It was found that average number of drugs per prescription was 5.45 which were almost similar to finding of Raj Kumar et al, 2013 and in contrast in other lisha jenny Johny et al, study in which 3.2+1.3 drugs were prescribed per prescription. The trend in this study showed that previous studies had positively influenced the diagnostic skills and the prescribing habits of doctors, though there is need for improvement.³⁵

Biguanides (Metformin), Sulphonylureas and Alpha-glucosidase inhibitor were the most prescribed anti-diabetic drugs where in sulphonylureas were most prescribed anti-diabetic drugs. Among the second generation sulphonylureas, glimepiride was the most commonly prescribed along with metformin which is in accordance with studies from H.B.Matalia et al,2011 Shaktibala Dutta, et al,2014⁵⁸.

The most commonly co-prescribed medication along with anti-diabetic drugs were hypolipidemic agents (Statin), followed by Angiotensin receptor blockers then antiplatelet drugs which was as same as Abdul Gafar O. Jimoh et al,2011 in which antihypertensive were most commonly co-prescribed medications.⁶⁰

A few percentages of patients were given injection due to the fact only type-2 diabetic patients were taken for the study of which they utilized mainly oral hypoglycaemic agents only. The most prescribed injection was insulin which is given in circumstances where hyperglycemia is not controlled by diet and exercise or when oral hypoglycemic agents fail to surpass the rise of blood sugar. Our study is contrast to H.B.matalia, et al study whereby insulin was highly prescribed followed by metformin and then glimepiride.⁶⁰

In this study the drugs were written with trade (non-generic) names, while none of the drugs was mentioned with their generic name, and drug from essential drug list were 40.23%. this further emphasizes the need to reduce the cost of medications to patients through increased prescription of their generic names and reduction in number of drugs per prescription to foster patients compliance and rational drug prescription without a fall in treatment standard towards attaining optimal diabetic control. Prescribing by generic name allow flexibility of stocking and dispensing various brand of a particular drug that are cheaper than and as effective as proprietary brands.



SUMMARY

SUMMARY

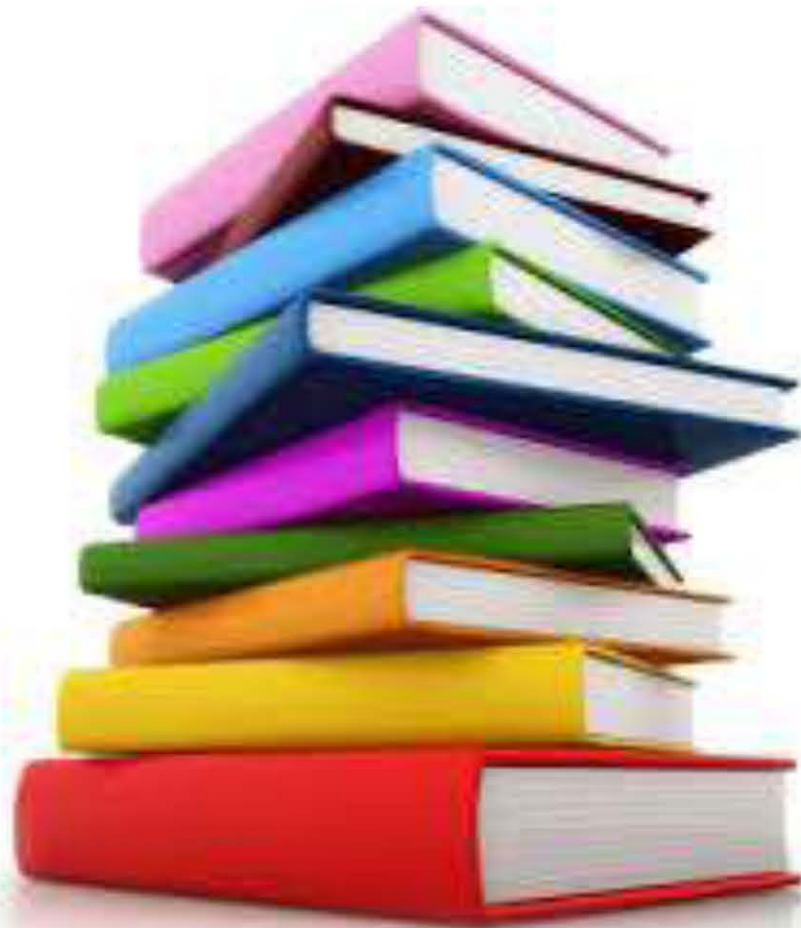
- A total of 110 patients who fulfilled both the inclusion and exclusion.
- The study revealed that type-2 diabetic mellitus affected male patients to a larger extend compared to the female patient. As shown in Table 1.
- Monotherapy was more utilized compared to other combination therapy. As shown in Table 5.
- Type-2 diabetic mellitus affected mostly elder people of age group 61-70. As shown in table 2.
- This study found out the Biguanides were commonly prescribed followed by Sulfonylurea. As shown in Table 5.
- It was found that some of type-2 diabetes mellitus patients had co-morbid diseases.

CONCLUSION

To conclude this, most of the prescription was rational, though further improvement is needed.

The study indicated that the choice of anti-diabetic remained more or less the same compared to previous studies. Type-2 diabetes mellitus is most common in elderly patients since the disease was more predominant in the age group of 61-70.

The study revealed metformin was most utilized anti-diabetic drug for type-2 diabetic patients. Most of diabetic patients have co-morbid conditions; therefore they require more than one medication for their proper care. It was compliant with NICE (National Institute for Health and Clinical Excellence) guidelines hence it was rational.



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ANNEXURE

PROFORMA

Name: IP.NO: AGE:

SEX: WEIGHT:

CHIEF COMPLAINTS:**PAST MEDICAL HISTROY :****PHYSICAL EXAMINATION:**

- TEMP :
- PULSE :
- BP:
- RR:

LABORATORY TEST:

Test	Date				
EPG					
BMI					
PPG					
HbA1C(%)					

PAST MEDICATION HISTROYDRUG CHAT:

T.NAME	G.NAME	DOSE	FRWQ	DATE											

SIGN:

PATIENT WRITTEN INFORMED CONSENT

I understand that my participation in voluntary and that I may withdraw from this study at any time without giving any reason or to answer any particular questions in the study. I consent the member of the study to have access to my response and public the result provided my identified is not revealed. I voluntary agree to participate in the study

Name and signature of the patient

Date :